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Remarks

Claims 1, 3 and 8 are amended. Claims 15-20 are new.  
Claims 1-20 will be pending upon entry of this amendment.

Response to Rejection of Claim 1 under 35 USC §102Claim 1

As amended, claim 1 is directed to a prosthetic elbow comprising, among other things, a humeral component including a generally cylindric spool being sized and shaped to fit within a recess formed between medial and lateral aspects of the condyle of the humerus. As shown best in Fig. 2 of the present application, the spool fits between the medial and lateral aspects of the condyle of the humerus, thereby preserving more bone stock than if the entire end of the humerus was removed. Preservation of the bone stock substantially maintains mechanical strength and function of the humerus and minimizes complications (e.g. fracture, hemorrhage). Moreover, the claimed prosthetic makes surgery less invasive, more repeatable and easier than if the entire end of the bone is removed. Moreover still, inserting the spool in a recess between the medial and lateral aspects of the condyle also facilitates bone growth into pores of the spool to achieve a well supported prosthetic.

More specifically, claim 1 recites a prosthetic elbow for attachment to a humerus and ulna, the prosthetic elbow comprising:

a humeral component comprising a generally cylindric spool having a contoured external surface defining a first articular surface, said spool being sized and shaped to fit

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within a recess formed between medial and lateral aspects of the condyle of the humerus;

a radioulnar component comprising a body having a generally U-shaped contour with an inner peripheral surface defining a second articular surface sized and shaped for engagement with the first articular surface and relative movement thereagainst.

Claim 1 is submitted to be unanticipated by and patentable over the references of record, and in particular U.S. Patent No. 4,038,704 (Ring), in that whether considered alone or in combination, the references of record fail to show or suggest a spool sized and shaped to fit within a recess formed between medial and lateral aspects of the condyle of the humerus.

Ring teaches an elbow prosthesis including a humeral member (10) with a cylindrical joint portion (12) having a central annular neck (13) in the shape of two coaxial frustocones abutting at their smaller ends. As illustrated in Fig. 1, at the larger ends of the frustocones, the joint portion has large cylindrical ends. The elbow prosthesis also includes an ulnar member (11) with a cuboid portion having a recess (17). The inner surfaces of the recess conform to the surfaces of the neck of the humeral member. The width of the cuboid portion is substantially the same as the axial length of the neck portion of the humeral member. See column 1, lines 37-42.

Ring does not teach that the cylindrical joint portion is sized and shaped to fit within a recess cut between medial and lateral aspects of the condyle of the humerus. Instead, it appears that the joint portion (12) is sized and shaped to replace the **entire** end of the humerus (i.e., including the condyles). The large cylindrical ends at the larger ends of the

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frustocones appear to act as the entire medial and lateral aspects of the condyle of the humerus and do not contact the recess (17) of the ulnar member. Only the annular neck (13) contacts the recess (17) of the cuboid portion of the ulnar member, as the width of the cuboid portion is substantially the same as the axial length of the neck portion of the humeral member. See column 1, lines 39-42.

The other references of record similarly fail to show or suggest all of the elements of claim 1.

For these reasons, claim 1 as amended is submitted to be patentable over the references of record.

Claims 2-7, 15 and 20 depend either directly or indirectly from claim 1 and are submitted to be patentable for the same reasons as claim 1.

#### Claim 8

Claim 8 as amended is directed to a prosthetic elbow comprising, among other things, a humeral component having a spool and a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, wherein at least a portion of the bore is completely surrounded by the spool. As shown in Fig. 5, for example, and described in the specification, the bore allows for a fastener to be inserted therein to attach the spool to the humerus. At least a portion of the bore is completely surrounded by the spool to ensure that the spool does not detach from the humerus when the fastener is received in the bore. For example, if there was a continuous opening along the length of the spool into the bore, then a fastener inserted into the bore may be able to pass through the opening, thereby allowing the component to detach from the humerus.

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More specifically, claim 8 recites a prosthetic elbow for attachment to a humerus and ulna comprising:

a humeral component comprising a generally cylindric spool having a contoured external surface defining a first articular surface;

a radioulnar component comprising a body having a generally U-shaped contour with an inner peripheral surface defining a second articular surface sized and shaped for engagement with the first articular surface;

wherein the humeral component has a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, at least a portion of the bore being completely surrounded by the spool, the humeral component being free of a stem for extending into a medullary canal of the humerus.

Claim 8 is submitted to be unanticipated by and patentable over the references of record, and in particular U.S. Patent No. 4,242,758 (Amis et al.), in that whether considered alone or in combination, the references fail to show or suggest a bore extending axially through a spool for receiving at least one fastener to attach the humeral component to the humerus, wherein at least a portion of the bore is completely surrounded by the spool.

Amis et al. disclose an elbow prosthesis with a humeral component (35). The humeral component has a substantially C-shaped cross-section and an inner surface (34) for engagement with the end of the humerus after the humerus has been trimmed to match the inner surface. See column 6, lines 2-25. As illustrated in Figs. 4-7, the humeral component is in the shape of a tube with the wall of the tube having a cut out portion

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(51) extending the **entire** length of the component. See column 6, lines 60-64. Amis et al. do not teach inserting a fastener into the humeral component to secure it to the humerus, but instead teach that the humeral component is fitted on the end of the humerus and may be secured using cement.

Amis et al. do not teach or suggest that at least an axial portion of the bore is completely surrounded by the spool. Instead, as stated above, Amis et al. teach that the humeral component has a cut out portion (51) extending the **entire** length of the component to allow the humeral component to be fitted on the end of the humerus. Amis et al. do not teach inserting a fastener in the humeral component to secure it to the humerus. Moreover, regardless of the lack of such teaching, inserting a fastener through the humeral component would not adequately secure the humeral component to the humerus because at no point along the length of the humeral component is the fastener entirely enclosed within the humeral component. Thus, no fastener can fix the location of the humeral component.

The other references of record similarly fail to show or suggest all of the elements of claim 8.

For these reasons, claim 8 is submitted to be patentable over the references of record.

Claims 9-14 depend either directly or indirectly from claim 8 and are submitted to be patentable for at least the same reasons as claim 8.

#### New Claim 16

New claim 16 is directed to a prosthetic elbow including, among other things, a humeral component having a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, wherein the humeral

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component is free of a stem for extending into a medullary canal of the humerus and the humeral component comprises a stabilizer extending axially from the spool for engaging the humerus to prevent rotation of the spool about the bore. This claimed construction allows for the spool to be fixedly attached to the humerus using the axial bore and the stabilizer without reaming the medullary cavity of the humerus to insert a stem of the humeral component. Accordingly, the surgery is less complicated and less invasive than surgery involving a humeral component with a stem.

More specifically, claim 16 recites a prosthetic elbow for attachment to a humerus and ulna comprising:

a humeral component comprising a generally cylindric spool having a contoured external surface defining a first articular surface;

a radioulnar component comprising a body having a generally U-shaped contour with an inner peripheral surface defining a second articular surface sized and shaped for engagement with the first articular surface;

wherein the humeral component has a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, the humeral component being free of a stem for extending into a medullary canal of the humerus, the humeral component comprising a stabilizer extending axially from the spool for engaging the humerus for fixation and prevention rotation of the spool about the bore.

Claim 16 is submitted to be patentable over the references of record in that whether considered alone or in combination, the references fail to show or suggest a humeral component

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having a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, wherein the humeral component is free of a stem for extending into a medullary canal of the humerus and the humeral component comprises a stabilizer extending axially from the spool for engaging the humerus for fixation and preventing rotation of the spool about the bore.

Applicants note that the Office opined in the present Office action that claim 9 was not patentable because Amis et al. teach walls (53, 55) acting as a stabilizer as claimed in claim 9. Applicants now assert that Amis et al. does not show or suggest a stabilizer that extends **axially** from the spool for engaging the humerus to prevent rotation of the spool about the bore. The axially extending stabilizer advantageously stabilizes the spool (i.e., prevents rotation) when both the humeral component is free of a stem and the spool is secured within a recess of the humerus by inserting the fastener through the bore. Ring similarly fails to show or suggest such a stabilizer recited in claim 16.

The other references of record similarly fail to show or suggest all of the elements of claim 16.

For these reasons, claim 16 is submitted to be patentable over the references of record.

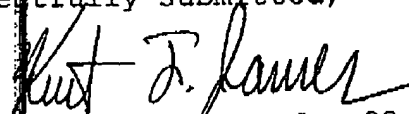
Claims 17-19 depend either directly or indirectly from claim 16 and are submitted to be patentable over the references of record for at least the same reasons as claim 16.

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Conclusion

In view of the foregoing, favorable consideration and allowance of claims 1-20 is respectfully requested.

Respectfully submitted,



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